

CRITERIA FOR PRIOR AUTHORIZATION

Botulinum Toxins

BILLING CODE TYPE For drug coverage and provider type information, see the [KMAP Reference Codes webpage](#).

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

OnabotulinumtoxinA (Botox®)
AbobotulinumtoxinA (Dysport®)
RimabotulinumtoxinB (Myobloc®)
IncobotulinumtoxinA (Xeomin®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.

CRITERIA FOR ONABOTULINUMTOXINA: (must meet one of the following): ^{1,2}

- For prophylaxis of headaches in patients with chronic migraines, refer to the migraine prophylaxis agents PA criteria.
- Treatment of upper limb spasticity in elbow, wrist, finger, or thumb flexors.
 - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of lower limb spasticity in patients to decrease the severity of increased muscle tone in ankle or toe flexors.
 - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of cervical dystonia.
 - Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
 - Must be prescribed by or in consultation with a dermatologist.
 - Prescriber must provide details of the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials.
- Treatment of blepharospasm associated with dystonia or strabismus.
 - Must be prescribed by or in consultation with a neurologist or ophthalmologist.
- Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency or urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g., spinal cord injury or multiple sclerosis).
 - Patient must have experienced an inadequate response after a 30-day trial of at least 2 anticholinergics at a maximum tolerated dose, OR have a documented intolerance or contraindication to therapy with anticholinergic medications.
 - Must be prescribed by or in consultation with a neurologist or urologist.

~~APPROVED DRAFT~~ PA Criteria

- Prescriber must provide details of the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials.

CRITERIA FOR RIMABOTULINUMTOXINB: (must meet all of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist.
- Must be being used for one of the following:^{1,3}
 - Treatment of cervical dystonia.
 - Treatment of chronic sialorrhea in adults.

CRITERIA FOR ABOBOTULINUMTOXINA: (must meet all of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist
- Must be being used for one of the following:^{1,4}
 - Treatment of cervical dystonia.
 - Treatment of upper limb spasticity.
 - Treatment of lower limb spasticity.

CRITERIA FOR INCOBOTULINUMTOXINA: (must meet one of the following)

- Must be prescribed by or in consultation with a neurologist or a physical medicine & rehabilitation specialist (or ophthalmologist for blepharospasm).
- Must be being used for one of the following:^{1,5}
 - Treatment of cervical dystonia.
 - Treatment of blepharospasm in adults previously treated with onabotulinumtoxinA.
 - Treatment of upper limb spasticity.
 - Treatment of chronic sialorrhea in adults.

LENGTH OF APPROVAL (INITIAL): 6 months. Subsequent authorizations will be granted for up to 2 injections in 6 months; injections must be at least 12 weeks apart, unless otherwise specified in Table 1.

CRITERIA FOR RENEWAL: (must meet all of the following)

- Subsequent authorizations will be granted for up to 2 injections in 6 months.
- Injections must be at least 12 weeks apart, unless otherwise specified in Table 1.

LENGTH OF APPROVAL (RENEWAL): 12 months

Notes: Use of Botulinum Toxins will **NOT** be approved for cosmetic purposes.

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for botulinum toxins.²⁻⁵

Agents	Indication(s)	Age	Dosing Limits
OnabotulinumtoxinA (Botox)	Adult upper limb spasticity	≥18 years	Up to 400 units every 12 weeks.
	Pediatric upper limb spasticity	≥2 to 17 years	6 Units/kg or 200 Units, whichever is lower <u>every 12 weeks.</u>
	Adult lower limb spasticity	≥18 years	Up to 400 units every 12 weeks.
	Pediatric lower limb spasticity, <u>excluding spasticity caused by cerebral palsy</u>	≥2 to 17 years	8 Units/kg or 300 Units, whichever is lower <u>every 12 weeks.</u>
	Cervical dystonia	≥18 years	Up to 300 units every 12 weeks.
	Severe axillary hyperhidrosis	≥18 years	Up 100 total units every 28 weeks.
	Blepharospasm	≥12 years	Up to 200 total units every 12 weeks.
	Strabismus	≥12 years	Up to 300 total units every 24 weeks.
	Overactive bladder	≥18 years	Up to 100 units every 24 weeks.
	Detrusor overactivity	≥18 years	Up to 200 units every 42 weeks.
RimabotulinumtoxinB (Myobloc)	Cervical dystonia	≥18 years	Up to 5,000 units every 12 weeks.
	Chronic sialorrhea	≥18 years	Up to 3,500 units every 12 weeks.
AbobotulinumtoxinA (Dysport)	Cervical dystonia	≥18 years	Up to 1,000 units every 12 weeks.
	Adults upper limb spasticity	≥18 years	Up to 1,000 units every 12 weeks.
	Pediatric upper limb spasticity, <u>excluding spasticity caused by cerebral palsy</u>	≥2 to 17 years	16 Units/kg or 640 Units, whichever is lower, <u>every 12 weeks.</u>
	Lower limb spasticity	≥18 years	Up to 1,500 units every 12 weeks.
	<u>Pediatric</u> Lower limb spasticity	≥2 to 17 years	15 Units/kg for unilateral lower limb injections, 30 Units/kg for bilateral injections, or 1000 Units, whichever is lower, <u>every 12 weeks.</u>
IncobotulinumtoxinA (Xeomin)	Cervical dystonia	≥18 years	Up to 120 units every 12 weeks.
	Blepharospasm	≥18 years	Up to 100 units (50 units per eye) every 12 weeks.
	Adult U pper limb spasticity	≥18 years	Up to 400 units every 12 weeks.
	<u>Pediatric upper limb spasticity, excluding cerebral palsy</u>	<u>≥2 years</u>	<u>8 Units/kg or 200 units for unilateral upper limb, 16 units/kg or 400 units for bilateral upper limbs every 12 weeks.</u>
	Chronic sialorrhea	≥18 years	Up to 100 units every 16 weeks.

References:

1. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology 2016; 86 (19): 1818-26. Available at <https://www.aan.com/Guidelines/home/GuidelineDetail/735>. Accessed 6/3/20.
2. Botox (onabotulinumtoxinA) [package insert]. Madison, NJ: Allergan USA, Inc.; ~~October~~ September 20192020.
3. Myobloc (rimabotulinumtoxinB) [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; October 2019.
4. Dysport (abobotulinumtoxinA) [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; ~~November~~ July 2020.
5. Xeomin (incobotulinumtoxinA) [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; ~~October~~ August 20192020.

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